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# Auricular acupuncture for insomnia

LENA BERGDAHL



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### **Abstract**

Bergdahl, L. 2017. Auricular acupuncture for insomnia. *Digital Comprehensive Summaries of Uppsala Dissertations from the Faculty of Medicine* 1330. 61 pp. Uppsala: Acta Universitatis Upsaliensis. ISBN 978-91-554-9905-1.

Cognitive behavioural therapy for insomnia (CBT-i) is the most effective treatment for insomnia. Studies show that auricular acupuncture (AA) may alleviate insomnia symptoms.

The overall aim of the thesis was to compare treatment effects of auricular acupuncture (AA) with cognitive behavioural therapy for insomnia (CBT-i) on symptoms of insomnia, anxiety, depression, hypnotic drugs consumption and quality of life from short- and long-term perspectives.

**Paper I** had a qualitative approach with a descriptive design. 16 participants received group-treatment with AA during their protracted withdrawal phase and were interviewed about their experiences. They participants experienced a reduction in protracted withdrawal symptoms, improved subjective sleep quality, a strong sensation of peacefulness and increased wellbeing.

**Paper II, III and IV** present results from a randomised controlled trial in where the effects of group-treatment with AA and CBT-i were compared in short- and long-term using subjective (questionnaires and sleep diary) and objective (actigraphy) measurements.

The results showed that CBT-i was superior to AA in reducing insomnia symptoms in both the short and long run. Both groups experienced significant long-term reduction of depressive symptoms. Further, both groups managed to maintain a decreased intake of hypnotic drugs at the end of the treatment when compared to baseline measurement. Short-term reduction of symptoms of anxiety and depression improved only in the AA group. The results from the objective actigraph recordings showed that the AA group slept more and the CBT-i group less after the treatment and that sleep patterns in both groups reverted to pre-treatment levels after 6 months.

Conclusively: AA, as administered in this study, was not as good as CBT-i in treating insomnia symptoms, and should not be used as a stand-alone treatment for insomnia. Our results also demonstrate that prolonged sleep time does not necessarily yield better sleep, and that the perception of insomnia symptoms is not inevitably affected by sleep duration. AA was as effective as CBT-i in ending hypnotic drugs consumption. Moreover, AA was more successful than CBT-i in reducing symptoms of anxiety and depression in the short run. Further studies investigating AA for anxiety and depression are motivated.

**Keywords:** auricular acupuncture, cognitive behavioural therapy, insomnia disorder, non-pharmacological, sleep disorder, treatment

*Lena Bergdahl, Department of Neuroscience, Psychiatry, University Hospital, Akademiska sjukhuset, Uppsala University, SE-751 85 Uppsala, Sweden.*

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### *Dedication*

This thesis is dedicated to my family who always believe in me, and in particular to my grandmother, Elsa Karlsson, who did not have the opportunity to obtain higher education but never stopped acquiring new knowledge.



# List of Papers

This thesis is based on the following papers, which are referred to in the text by their Roman numerals.

- I Bergdahl L, Berman AH, Haglund K.  
Patients' experience of auricular acupuncture during protracted withdrawal  
*Journal of Psychiatric and Mental Health Nursing*. 2014; 21(2): 163-169.
- II Bergdahl L, Broman JE, Berman AH, Haglund K, von Knorring L, Markström A. Is Auricular Acupuncture as effective as Cognitive Behavioural Therapy for insomnia?  
*Sleep Disorders*. 2016; 2016: 7057282.
- III Bergdahl L, Broman JE, Berman AH, Haglund K, von Knorring L, Markström A. Auricular acupuncture versus cognitive behavioural therapy in the discontinuation of hypnotic drug usage and treatment effects of anxiety, depression and insomnia symptoms  
Submitted to *European Journal of Integrative Medicine*
- IV Bergdahl L, Broman JE, Berman AH, Haglund K, von Knorring L, Markström A. Sleep patterns in a randomised controlled trial of Auricular Acupuncture and Cognitive Behavioural Therapy for insomnia  
Submitted to *Complementary Therapies in Clinical Practice*

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# Contents

Introduction .....	11
Insomnia .....	11
Consequences of insomnia.....	11
Measurements of insomnia .....	12
Treatments of insomnia.....	12
Acupuncture.....	13
Challenges in acupuncture trials .....	15
Expectations and placebo response.....	15
Rationale .....	16
Aims .....	17
General aim.....	17
Specific aims.....	17
Methods.....	18
Patients' experience of auricular acupuncture during protracted withdrawal (Paper I) .....	18
Design .....	18
Participants.....	18
Measurements.....	19
Intervention .....	19
Procedure .....	19
A randomised controlled trial of AA and CBT-i (Papers II, III and IV).....	20
Design .....	20
The participants.....	20
Measurements .....	20
Interventions .....	23
Procedure .....	24
Ethical consideration.....	27
Data analysis .....	27
Statistical analyses in Paper II, III and IV .....	28

Results .....	29
Patients' experience of auricular acupuncture during protracted withdrawal (Paper I) .....	29
Is Auricular Acupuncture as effective as Cognitive Behavioural Therapy for insomnia? (Paper II) .....	29
Comparison between the CBT-i and the AA groups .....	29
Within-group results .....	30
Auricular acupuncture versus cognitive behavioural therapy in the discontinuation of hypnotic drug usage and treatment effects of anxiety-, depression and insomnia symptoms (Paper III) .....	33
Hypnotic drugs .....	33
The questionnaires .....	33
The sleep diary .....	36
Sleep patterns in a randomised controlled trial of Auricular Acupuncture and Cognitive Behavioural Therapy for insomnia (Paper IV) .....	39
Actigraph recording - within-groups results .....	39
Actigraph recording - between-groups results .....	41
SF-12 .....	44
Discussion .....	46
Main results .....	46
Effects on insomnia symptoms .....	46
Effects on related symptoms .....	47
Discontinuations of hypnotic drugs .....	48
General discussion .....	49
Clinical relevance .....	49
Suggestions for future research .....	49
Limitations .....	50
Conclusions .....	51
Paper I .....	51
Paper II .....	51
Paper III .....	51
Paper IV .....	51
Acknowledgement .....	53
References .....	56



# Abbreviations

Auricular acupuncture (AA)

Cognitive behavioural therapy for insomnia (CBT-i)

Cohen's delta (Cohen's d)

Diagnostic and statistical manual of mental disorders, fifth edition (DSM-5)

Dysfunctional Beliefs and Attitudes about Sleep scale (DBAS-16)

Epworth Sleepiness scale (ESS)

Health-related quality of life (HRQoL)

Hospital Anxiety Depression scale (HAD)

Insomnia Severity Index (ISI)

Mental component summary (MCS)

National Acupuncture Detoxification Association (NADA)

Parameter estimate (PE)

Physical component summary (PCS)

Polysomnography (PSG)

Randomized controlled study (RCT)

Short Form 12 (SF-12)

Short Form 36 (SF-36)

Standard deviation (SD)

Standard error (SE)



# Introduction

Sleep is fundamental to all living species, and although scientific research has been a huge force in helping us to understand why we sleep, it is still a relatively unsolved mystery. We do know that sound sleep can help prevent sickness and maintain good health, whereas sleep deprivation can lead to serious health consequences and increased sleep-related accidents. In our modern 24-hour society in which rotating shift-work is common and the borders between work and leisure are no longer fixed, there is greater risk to develop sleep disorders [1][2][3].

## Insomnia

Insomnia is a common and growing problem and is approximately twice as common for women as for men [e.g 4], 14 respectively 7% [5]. In addition to an unsatisfactory sleep quality, insomnia disorder is diagnostically characterised by difficulty in falling asleep, involuntary and/or early awakenings more than three times a week for more than 3 months, and daytime impairment affecting central cognitive functions [6].

According to investigations of living conditions by Statistics Sweden (SCB) sleep is an indicator for public health, where insomnia is among the five most common causes for drug prescriptions. Two out of three recipes for hypnotics within the primary care are system prescribed to women and more than half of these are prescribed to persons >65 years [5].

## Consequences of insomnia

Insomnia symptoms and related daytime symptoms are subjective [7][8] and may cause a significant personal distress and/or impair a person's ability to function (not to mention increased costs for society).

On an individual level insomnia generates increased risk for other comorbidities such as anxiety disorders, depression [9][10][11] and clinical burn-out [12]. In addition, insomnia increases the risk of developing cardiovascular disease [13][14], type 2 diabetes [15][16], a weakened immune system [15] and obesity [17]. It may also increase the risk of drug dependence [5]. On a societal level, the largest insomnia-related costs are represented by

increased sick leave, loss of production [18][19][20], disability pension [21] and traffic- and fall accidents [5][22]. In 2008, the insomnia related costs were calculated to 3 billion Swedish crowns, where 1 billion crowns were direct and 2 billion were indirect costs [5].

## Measurements of insomnia

Insomnia can be measured either subjectively or objectively [e.g., 23]. When establishing an insomnia diagnosis, standard procedure is to combine a clinical interview according to the diagnostic and statistical manual of mental disorders, 5<sup>th</sup> edition (DSM-5) [6] in conjunction with self-report questionnaires. A sleep log or a sleep diary can be used to observe sleep-wake patterns.

The golden standard of objective sleep disturbance measurements is polysomnography (PSG) [24]. Although PSG can determine different sleep stages including total sleep time, it is not primarily used to diagnose insomnia but rather other sleep disorders, such as parasomnia, narcolepsy and sleep-disordered breathing disorders [24]. Actigraphy, a non-invasive method of monitoring rest/activity movements that can be used to estimate sleep parameters, is another objective measurement method, in which sleep-wake patterns can be studied by assessing movement [25]. According to a review by Ancoli-Israel et al. (2003), the validity and reliability of actigraphy is moderate to high in differentiating waking states from sleep in a healthy population [25]. In a study by Vallières et al (2003) in which actigraphy was compared with PSG and a sleep diary, the actigraphy was confirmed as a reliable method to assess insomnia[26]. To obtain reliable information in sleep parameters, monitoring for a minimum of 7 days is required [27].

Important to note, however, is that the objective and subjective measurements do not always correlate. While objective measurements can, for instance, show improved actual sleep time after a treatment, the subjective measurements may not necessarily reflect the results [28][29][30][31].

## Treatments of insomnia

Treatment for insomnia can be pharmacological, non-pharmacological or a combination of both. General advice about sleep hygiene combined with sleep medication is the most common treatment method [5].

### **Hypnotic drugs**

Non-benzodiazepines, also known as z-drugs, are a common pharmacological treatment for insomnia. Although pharmacological treatment may be effective, there may also be serious side effects (e.g., drug dependence and residual daytime sedation). Usage should be limited to 4–6 weeks to avoid

potential side effects. Prescription studies, however, show that many patients, especially the elderly, receive pharmacological treatment over long periods [5][32]. There are also gaps in research regarding the long-term effectiveness of non-benzodiazepines [33].

### **Cognitive Behavioural therapy for insomnia (CBT-i)**

Research on insomnia over the past two decades shows a trend towards increased non-pharmacological research, in which behavioural therapies are emphasised [34].

Based on previous research, cognitive behavioural therapy (CBT) [5][35] is the most effective treatment option, and it is also recommended as the first choice of treatment [5]. CBT is a psychotherapeutic treatment method that includes cognitive and behavioural therapy whereby the patient is actively working to change thoughts, emotions and patterns that are non-health promoting. CBT for insomnia (CBT-i) consists of sleep-focused manual-based treatment sessions that include stimulus control, sleep restriction, cognitive strategies, relaxation techniques and sleep hygiene [e.g 36]. The treatment goal is to identify and change the behavioural, psychological and physiological factors that maintain insomnia. However, CBT-i may not be suitable for everyone. According to a review by Harvey et al., (2003) CBT seemed less effective for treating insomnia compared with treating other psychological disorders [37]. The authors have proposed potential ways to improve CBT-i delivery. Montserrat Sánchez-Ortuño et al. (2010) hypothesised the existence of sub-groups among patients with insomnia that may respond differently to manual-based CBT [38]. Thus investigating the effectiveness of other non-pharmacological treatment options seems to be warranted.

### **Acupuncture**

Acupuncture is a non-pharmacological treatment method based in traditional Chinese medicine. Interest in acupuncture as a complement to conventional medicine has increased over the past years and has, to some extent, entered the ordinary healthcare system [39].

Auricular acupuncture (AA) is a branch of acupuncture in which thin, sterile, stainless needles are inserted into definite points on the surface of the outer ears. The French physician Paul Nogier, developed the method in the 1950s [40]. AA has been used within psychiatric care, mainly for substance dependence [41]. Within the substance dependence care, AA according to the NADA (National Acupuncture Detoxification Association) protocol is used. The NADA protocol (Fig. 1) was developed in the USA during the 1970s and is used to support patients with substance abuse to treat withdrawal symptoms [42][43].

The physiological mechanisms of AA have been systematically studied, and the explanatory mechanistic model argues that the autonomic nervous

system can be affected through the auricular branch of the vagus nerve by stimulation of acupuncture needles or by pressure [44][45][46]. In a study by Haker et al. (2000) stimulation of the AA point Lung instantly increased parasympathetic activity [44]. Hsu et al. (2007) reported a similar result when stimulating the AA point Shen Men [45].

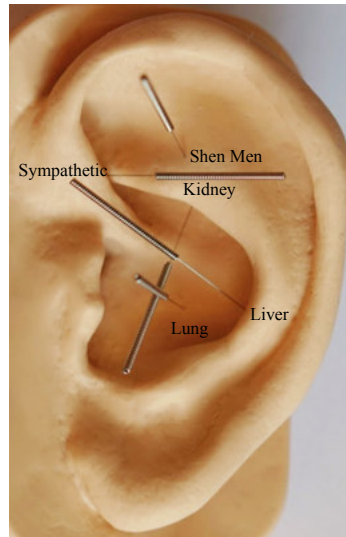


Figure 1. Acupuncture points according to the NADA protocol: Shen Men, sympathetic, kidney, liver and lung

### **Auricular acupuncture for insomnia**

Acupuncture, and to some extent AA [47], has previously been used to treat insomnia [48][49][50][51][52][53]. Berman et al. (2004) conducted a randomised controlled study in which inmates from two prisons, all with prior identified drug use, received AA treatment. Subjective improved sleep quality was reported as a treatment side effect by the participants [54]. An earlier, randomised trial found modest improvements (with fewer awakenings in the standard treatment group) for several sleep parameters for women in psychiatric care randomised to AA treatment according to standard or sham protocols [47]. In a recent study by Ahlberg et al. (2016), acupuncture insertion based on the NADA protocol was administered to two groups of patients: one group received 15 treatments and the other 10. Symptoms of insomnia and anxiety were reduced in both groups [55].

A meta-analysis of 33 studies in which different forms of acupuncture were used to treat insomnia could only show that AA may ameliorate poor sleep quality compared with placebo; i.e. definite conclusions could not be drawn because of the low methodological quality of the studies under investigation. Further empirical research with more stringent methodology was recommended to assess the effectiveness of AA for insomnia[51].

## Challenges in acupuncture trials

When planning the design of a clinical acupuncture trial, there are several challenges that need to be addressed. One such challenge concerns the configuration of the control group. Should one use unspecified acupuncture points, superficial needling, or “sham needles” that trick the receiver to believe there is an actual needle placed in the skin, or should one simply press the points manually? Because the goal of a control group is to separate the effect of the true treatment from false treatment, it is extremely important to choose the appropriate arrangement for the control group. Dincher and Linde (2003) discussed the challenges in choosing appropriate control methods in acupuncture trials, emphasising the need to fully understand which question the setup will answer. For instance, to use non-penetrating (placebo) needles at non-acupuncture points could serve to answer the question of whether skin penetration and localisation make a difference, but it does not answer questions related to treatment efficacy. One of the issues of using sham acupuncture is that the manipulation that does occur partly activates the sensory pathways, which may subsequently lead to a physiological response. If the physiological response from the sham needling is not taken under consideration, the purpose of the control group is lost and there is no way to know with certainty what is the specific and non-specific treatment effect [56]. Birch (2003) and Huang et al. (2011) addressed these technical issues and discussed the difficulties in creating a sham acupuncture procedure that is physiologically inactive as well as psychologically trustworthy [57][58]. If sham acupuncture is the choice of control the researcher must take the metameric structure of the body under consideration to create a trustworthy placebo group [59].

In the randomised controlled trial (RCT) used in this thesis, we chose to handle this issue by using a completely different treatment method as a control group. Specifically, we chose CBT-i because it is the best non-pharmacological treatment method for insomnia. It is a challenge to design a rigorous acupuncture trial, and the documented effectiveness of CBT-i was the main reason to choose it as a control treatment.

## Expectations and placebo response

Expectations (from both patient as well as professional caregiver) are an element included in all treatments and may indeed affect the outcome. It is well-known that the social participant-clinician interaction affects treatment outcome [60], and acupuncture is no exception [61][62]. Situational factors (e.g., treatment setting, rituals and the therapist’s behaviours and expressions) may trigger a placebo response [63]. Consequently the event of simply being included in a study/intervention is a powerful parameter. It is also

known that persons who knowingly receive open-label placebo treatment in trials may show significant treatment results [64].

## Rationale

In Paper I, almost all respondents reported an increased sense of wellbeing and relaxation, where the decreased stress level helped them to improve their subjective sleep quality. The results from Paper I raised the question of whether the results would be transferable to treat insomnia. Our main goal was to determine whether the subjective improvements reported in Paper I could be measured quantitatively. Thus, a RCT was conducted with the following hypothesis: “Is AA as good as or better than CBT-i in the treatment of insomnia?”.



# Aims

## General aim

The general aim of the thesis was to compare treatment effects of AA with CBT-i on symptoms of insomnia, anxiety, depression and quality of life from short- and long-term perspectives.

## Specific aims

- The aim of Paper I was to determine how participants experienced receiving AA according to the NADA protocol during their protracted withdrawal phase.
- In Paper II, the primary aim was to compare treatment effects of AA with CBT-i and evaluate symptoms of insomnia severity from short- and long-term perspectives. Symptoms of anxiety and depression were also evaluated.
- Paper III aimed to assess the immediate treatment effects of AA and CBT-i in relation to discontinuation of hypnotic drug usage, symptoms of anxiety, depression and insomnia as well as other sleep parameters.
- The aims of Paper IV were to use an objective measurement method, actigraphy, to examine how sleep patterns were affected in the short- and long-term perspective after AA- or CBT-i, as well as to compare sleep parameters related to these patterns between the two treatment forms.

# Methods

## Patients' experience of auricular acupuncture during protracted withdrawal (Paper I)

### Design

A qualitative approach with a descriptive design [65] was used to describe the patient experiences of receiving AA treatment.

### Participants

Participants at an addiction outpatient clinic associated with a large university hospital in Sweden were recruited to this study. Patients who had ended their problematic alcohol and/or drug use and who were still in a protracted withdrawal phase were eligible to participate. Exclusion criteria were pregnancy, patients with psychosis and patients whose responsible physician, the chief of medicine or other delegated physician felt (for whatever reason) the patients were not capable of participating in the study. The final sample consisted of patients who, in addition to their problematic substance use, had psychiatric health problems such as anxiety and mood disorders. All patients had access to treatment as usual at the clinic during the study. Of 21 consent forms delivered to patients, 18 (86%) were signed and returned. One person dropped out before the study started, leaving a group consisting of 4 men and 13 women in the aged range, 28–63 years. This group was deemed a purposeful sample, representative of all patients at the clinic during the time the study was conducted.

Four participants were treated for the first time, whereas the rest had been treated previously at the clinic. 15 participants had been diagnosed with alcohol dependence in remission and 1 of these was medicated with methadone. Three respondents had a prior addiction to benzodiazepines and 3 respondents had had both alcohol and benzodiazepine dependence. One participant dropped out for unknown reasons, leaving 16 participants who completed the study.

## Measurements

Interviews were conducted and recorded for 16 patients.

The interview questions were as follows:

- What is positive about receiving AA treatment?
- What is negative about receiving AA treatment?
- Has the treatment changed your life in any way?

## Intervention

All participants were offered AA therapy according to the NADA protocol twice a week for 5 weeks in a group setting. At each treatment, 5 sterile, disposable stainless acupuncture needles were inserted bilaterally in each participant's external ear surface for about 40 minutes. Before inserting the needles, the participants' outer ears and the acupuncturists' hands were cleaned with a disinfectant solution. During the sessions, the participants sat in a comfortable chair and were instructed by the acupuncturist to close their eyes and focus on maintaining a calm and regular breathing pattern. After the final session all participants were interviewed about their treatment experiences.

## Procedure

Data were collected between January and October 2010.

Each patient's usual treatment provider at the clinic gave eligible participants written and oral information about the study. The participants were not economically compensated but they did receive free treatment. The third author, a registered nurse and PhD with extensive experience in conducting research interviews, conducted the interviews following the treatment. The interviews took place in privacy at the hospital or at the facilities of the Department of Neuroscience, Uppsala University.

The interviews, always with the patients' permission, were audio-recorded and the average duration of the interviews was 19 minutes. Because of technical issues, one of the interviews was not possible to transcribe, thus 15 interviews were transcribed. The first author was previously known to the patients, whereas the second and third authors were not connected to the clinic and thus had no previous contact with the patients. The third author had no prior knowledge about acupuncture.

## A randomised controlled trial of AA and CBT-i (Papers II, III and IV)

### Design

This was a prospective RCT evaluating immediate and long-term AA and CBT-i treatment effects.

### The participants

Inclusion criteria were men and women (aged 18-75 years) with insomnia, diagnosed according to the DSM-5 [6]. They all had been using non-benzodiazepine hypnotics at least three times a week for 6 months or more, and expressed a willingness to discontinue their medication. To participate they had to understand the Swedish language (written and spoken). Exclusion criteria were substance dependence (alcohol or drugs), patients with severe psychiatric disorder, severe somatic disease, pharmacological treatment with anti-psychotic medicine and/or morphine- /morphine-like medication, patients who had initiated antidepressant- or anxiolytic- treatment within the past 3 months, or pregnancy.

The final sample, comprising 50 women and 9 men (mean age 60.5 years, SD 9.4 years), had a mean body mass index (BMI) of 25.2 (SD 3.8), and were suffering from insomnia for more than 6 months. Despite pharmacological treatment during a mean of 7.3 (SD 5.6) years with a mean consumption of 5.8 (SD 3.1) tablets per week, the participants had residual insomnia symptoms, which led them to a desire to discontinue their medication. Of the 59 participants, 26 were retired, 29 were working and one was studying. The other three participants were on long-term sick-leave or had disability pension; one of these three participants was unemployed.

### Measurements

Three tools were used in this study: validated questionnaires, actigraphy and a sleep diary. For the questionnaires (Fig. 2), measurements were taken at baseline, pre-treatment (i.e. the same day as the treatment started), directly after treatment (i.e. the same day as the treatment ended), post-treatment (i.e. 1 week after treatment ended) and 6 months after treatment. Registration with actigraphy was done at baseline, post-treatment and at the 6-month follow-up. The registration was performed for 7 days at each measurement point. The sleep diary was filled out by the participants from baseline to post-treatment (i.e. throughout the intervention period) and for 7 days at the 6-month follow-up.

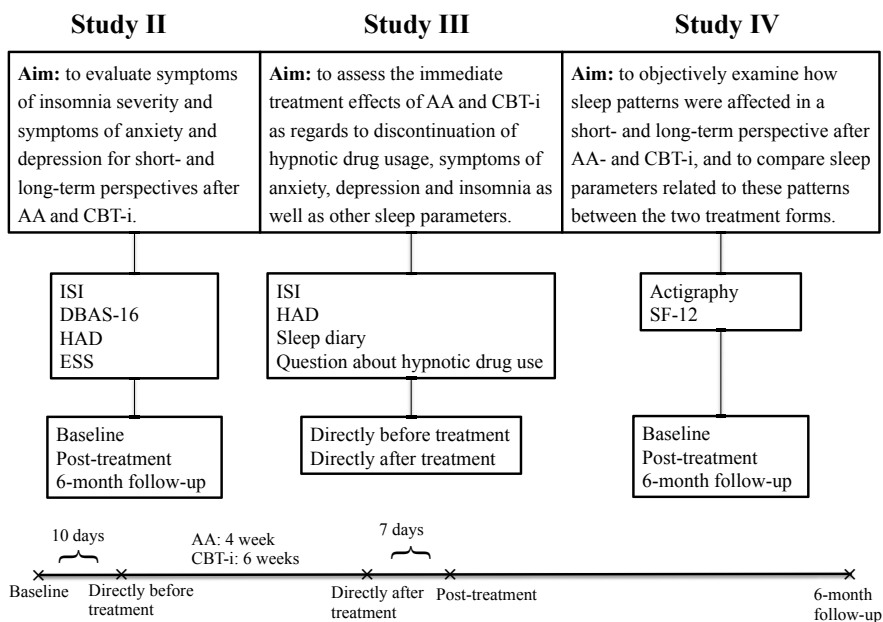


Figure 2. Aims and methods of the measurements for Studies II, III and IV, including the timeline of the measurement points.

## Questionnaires

### *Insomnia Severity Index (ISI)*

ISI is a seven-item questionnaire assessing the severity of insomnia as regards to sleep-onset and maintaining of sleep, the satisfaction with current sleep pattern and the interference with daily functioning, impairment due to sleep problems and level of distress caused by insomnia. A four-point rating is used: for example, for item seven, 0 indicates “Not at all interfering” and 4 “Very much interfering”. A total score is obtained by adding the scores for all seven items (lowest score = 0, highest score = 28). A high score (22-28) indicates severe clinical insomnia [66]. A change score in ISI greater than seven suggest as a moderate improvement of insomnia symptoms, whereas a change score of nine is regarded as marked improvement [67].

### *The Dysfunctional Beliefs and Attitudes about Sleep scale (DBAS-16)*

Previous studies have reported an association between the level of insomnia severity and dysfunctional beliefs about sleeplessness [68][69]. Thus the DBAS-16, a 16-item self-report questionnaire, was used to detect subjective beliefs, worries and expectations concerning the participants’ sleep, sleeplessness and sleep medication [70]. For each of the 16 statements, the participants rate their level of agreement/disagreement on a 10-point Likert-type scale from 0 (“Strongly disagree”) to 10 (“Strongly agree”). The total score

is 10, where a high score indicates more severe dysfunctional thoughts and beliefs [71].

#### *Epworth Sleepiness scale (ESS)*

To measure daytime sleepiness, the ESS was used. The questionnaire contains eight items that are rated on a scale from 0 (“No chance of dozing” to 3 (“High chance of dozing”). This simple scale describes everyday situations that may induce sleepiness. The total score ranges from 0-24, with a score >9 indicating excessive daytime sleepiness [72].

#### *Hospital Anxiety Depression scale (HAD)*

The HAD was used to determine the occurrence and evaluate symptoms of anxiety (HAD-A) and/or depression (HAD-D). The anxiety and depressive subscales each contain seven items, with each item rated on a scale from 0-3, which means that a person can score between 0 and 21 for either anxiety or depression. A score above 8 indicates presence of anxiety or depression [73].

#### *Short Form Health Survey (SF-12)*

Health-related quality of life (HRQoL) was also assessed with the SF-12. The SF-12, a 12-item health questionnaire, is an abbreviated version of the more extensive form SF-36 instrument. It covers both physical (physical component summary, PCS) and mental (mental component summary, MCS) components of health [74]. Each of the 12 items is rated on a scale from 0 to 100, with the lowest number (0) indicating maximum disability and the highest number (100) no disability.

#### *Actigraph recordings*

The MotionWatch 8® Actigraph, (CamNtech Ltd, Cambridge, UK) was used to assess each participant’s 24-hour activity pattern and to distinguish states of sleep from states of wakefulness.

The MotionWatch 8 is a light-weighted, wrist-worn tri-axial accelerometer designed to monitor long- or short-term activity. Its sensitivity for movement lies within 0.01 g to 8 g and 3 to 11 Hz. The recorded movements are measured in epochs (i.e time intervals). In the present study the chosen time interval was 1-minute epochs. The participants used an event button to indicate what time they went to bed in the evening and the time they rose in the morning.

MotionWare 1.1.20 Software was used to download and store data as well as to activate the scoring algorithm that provided the estimates of the various sleep parameters. The following sleep parameters derived from the software were: Bedtime, Fell asleep, Woke up and Rising, Total time in bed (i.e. the total elapsed time between “Bedtime” and “Rising”), Sleep efficiency (i.e. actual sleep time expressed as a percentage of time in bed), Sleep latency (i.e. the time between Bedtime and Fell asleep), Actual sleep time (i.e. the

total time spent in sleep according to the epoch-by-epoch wake/sleep categorisation) and Actual wake time (i.e. the total time spent in a wakeful state according to the epoch-by-epoch wake/sleep categorisation). All parameters were estimated in minutes, except for sleep efficiency, which was estimated in percentages.

An experienced sleep technician performed all analyses.

### *Sleep diary*

A sleep diary was filled in throughout the intervention period. The sleep diary was a part of the material used in the CBT-i manual [75]. The diary is divided into a night- and a day section. The night section contains information about total sleep time, time spent in bed and sleep onset latency (i.e. number of minutes it took to fall asleep after going to bed). There was also an option to register the number of awakenings. The day section contains information about different psychical and psychological daytime symptoms, as well as the opportunity to give comments about the use of hypnotics, alcohol intake, naps during the day and so on.

## Interventions

### **Auricular acupuncture AA**

The AA group received treatment twice a week for 4 weeks. The standardised insertion pattern, defined as the NADA protocol [42][43] was applied.

All treatments were carried out in hospital facilities and were performed by two AA- trained members of the psychiatric medical staff. At each session the participants received 5 acupuncture needles (depth 3 millimetres) in the outer ears, for a period of 45 minutes. No needle stimulation was performed. During treatment, the participants sat in a chair and were instructed by the acupuncturist to close their eyes and to focus on keeping their breathing calm and regular. To keep the treatment conditions as similar as possible for all participants, the acupuncturists maintained the same attitude and demeanour throughout the study. When the needles had been inserted the acupuncturist immediately left the room. At the end of the treatment session the acupuncturist removed the needles.

Disposable, sterile stainless Zhongyan Taihe acupuncture needles (0.18 x 13 mm) were used. Before the needles were inserted into the participants' outer ears the acupuncturists' hands and the participants' outer ears were disinfected with disinfectant solution approved for its efficacy.

### **CBT-i**

The CBT-i group received manual-based group treatment [75] that focused on cognitive restructuring, once a week for 6 weeks. The sessions contained information on sleep physiology, ways to cope with sleeping problems, sleep

restriction, maintaining factors and stimulus control and relaxing techniques (Table 1). Each session lasted for approximately 90 minutes.

Three registered psychologists, who all had undergone CBT training and were experienced in CBT-i treatment, carried out the treatments. All sessions were performed in hospital facilities.

Session	Content
1	<ul style="list-style-type: none"> <li>• Introduction</li> <li>• Going through the treatment rational and introducing the sleep diary</li> <li>• Presenting the concept of self help, i.e. emphasising the importance of taking control over the sleep pattern, and increase the effectiveness of coping with insomnia</li> <li>• Expectations</li> </ul>
2	<ul style="list-style-type: none"> <li>• The biology of sleep</li> <li>• The function of sleep</li> <li>• Sleep restriction</li> </ul>
3	<ul style="list-style-type: none"> <li>• Stimulus control</li> </ul>
4	<ul style="list-style-type: none"> <li>• Visualisation</li> <li>• Relaxing techniques</li> </ul>
5	<ul style="list-style-type: none"> <li>• Negative self-talk</li> <li>• Automatic thoughts</li> </ul>
6	<ul style="list-style-type: none"> <li>• Problem solving</li> <li>• Sleep hygiene</li> </ul>

Table 1. The content of all six CBT-i sessions

## Procedure

Participant inclusion into the study took part between January 2013 and October 2014. The participants were recruited by advertisement in the local newspaper and from an outpatient sleep clinic. The general procedure from enrolment to analysis is described in Figure 3. Before inclusion, the potential participants were interviewed by telephone by the first author (LB) who was the first person to assess the potential participants. The inclusion took part at a clinical meeting with the last author (AM) who assessed all participants before inclusion.

After inclusion the participants were randomised to group treatment with AA or CBT. The randomisation procedure was carried out by means of a pre-study randomisation list. A block randomisation was used in which each group contained five positions for each treatment. The investigators were



informed of each individual randomisation and the participants were coded according to the groups and registered in the medical chart.

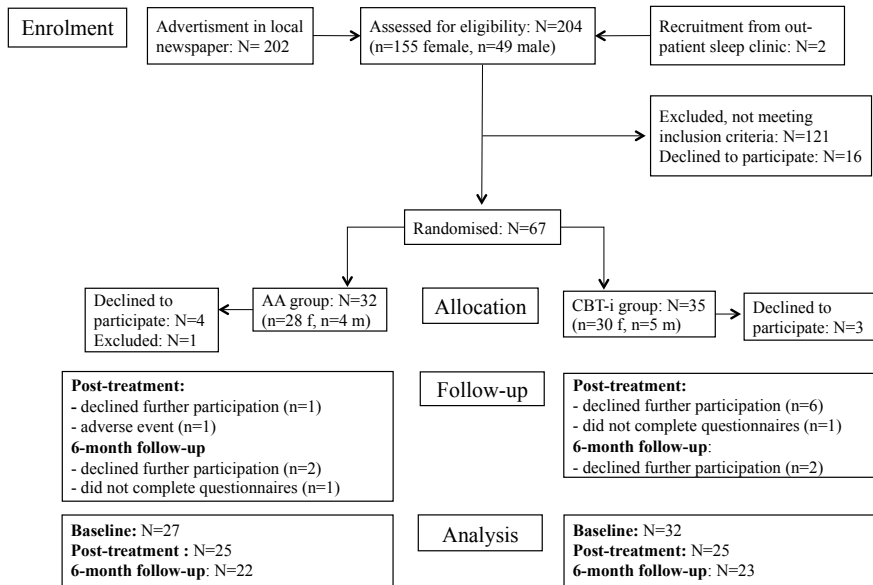


Figure 3: CONSORT flow diagram of events and participants during the study.

Both papers II and IV were short- and long-term studies. In Paper II, measurements were made with the ISI, DBAS-16, ESS and HAD at three time points; at baseline, 1 week after the intervention and at the 6-month follow-up. The ISI was used as the primary outcome measure.

In Paper IV, actigraphy recordings were used to evaluate the short- and long-term treatment effects of AA and CBT-i treatment. Measurements were made for 7 executive days at 3 time points (i) baseline, (ii) directly after the treatment had finished, and (iii) 6 months after the treatment had ended. The SF-12 questionnaire was used to assess HRQoL at baseline, 1 week after the treatment was over, and at the 6-month follow-up. The CONSORT flow diagram over the actigraphy procedure in Paper IV is presented in Figure 4.

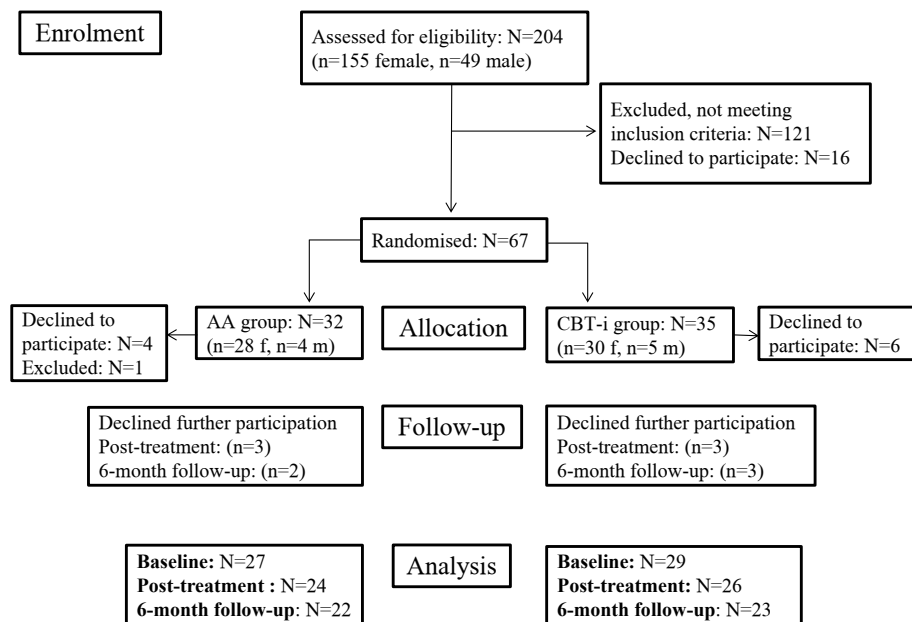


Figure 4: CONSORT flow diagram over number of participants in Paper IV.

In Paper III, which was a short-term study, three measuring instruments were used (ISI, ESS and HAD). Measurements were taken on the first day of treatment just before the intervention was initiated, and directly after the last treatment session. Information from the sleep diary, which also contained an inquiry about hypnotic consumption, was analysed.

The weekly mean of the participants' hypnotic drug usage was measured over time from baseline (i.e., 10 days before the intervention to treatment start and from baseline to the end of treatment) and from treatment start to completion. Measurements were made between and within the CBT-i and AA groups. The CONSORT flow diagram over the procedure in Paper III is presented in Figure 5.

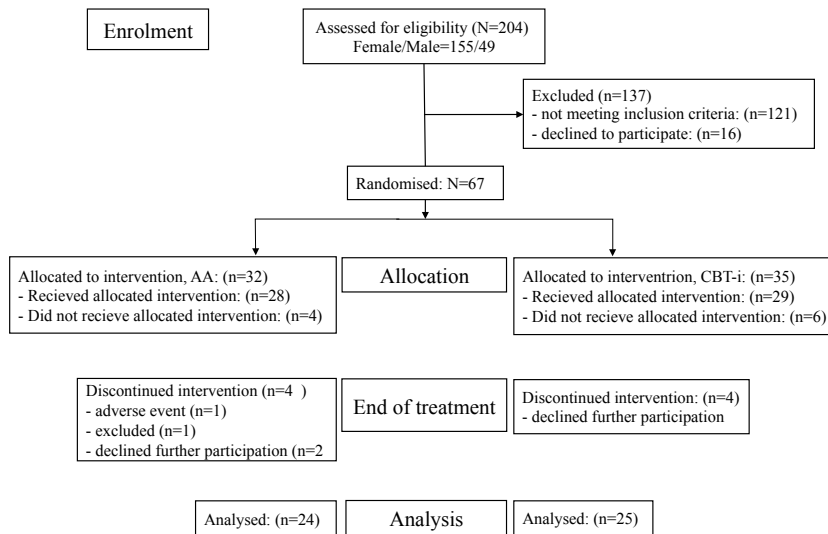


Figure 5: CONSORT flow diagram and passage of events before and after the intervention in Paper III.

## Ethical consideration

The studies were conducted in accordance with the principles of the Helsinki Declaration [76] and ethical approval was obtained from the Regional Ethical Review Board, Uppsala University, Sweden for Paper I (reference number 2009/372) and for the RCT in Papers II, III and IV (reference no: 2012/353). The RCT was also registered in the ClinicalTrials.gov database (ClinicalTrials.gov ID: NCT01765959).

All participants were provided with written and oral information about the study. They were informed that participation was voluntary and that they could withdraw from the study at any time without consequences or having to reveal why. All participants signed an informed consent before participating in the intervention.

## Data analysis

### Paper I

Qualitative content analysis [77] was used to analyse the interview transcripts[78]. The questions asked were what was positive / negative about receiving AA and whether it had changed some parameters in the participant's life. All interviews were transcribed and numerically coded. The texts were read and re-read multiple times to gain optimal understanding of the content. Then the texts were sorted under headings in the form of sentences consisting of relevant information. Next the sentences were condensed into meaning units summarising the core of the unit. Thereafter the meaning units

were classified into codes. Finally, categories were created in which similar answers were placed.

The first and third authors performed the analysis and discussed the results with the second author, a licensed clinical psychologist and senior researcher who is also qualified to provide AA treatment.

Meaning unit	Code	Subcategory	Category
There are no tablets in the whole world that make you feel this peaceful and harmonious...	Better than tablets	Harmonious	Peacefulness and harmony
...I slept for twelve straight hours...	12 hours of sleep	Sleep	Relaxation and well-being

Table 2. Example of how to create meaning units, codes, subcategories and categories.

## Statistical analyses in Papers II, III and IV

To examine treatment effects over time a series of linear mixed models, using the restricted maximum likelihood method and unstructured variance components, was estimated with the ISI, ESS, DBAS-16, HAD and SF-12 questionnaires, as well as the sleep diary parameters and actigraphy recordings as outcome variables. Treatment group, sex, measurement point, time on medication, age, and the interaction of treatment group and measurement point were chosen as fixed factors/covariates. Dropouts were assessed using the Pearson chi-square test and the Mann-Whitney test. The level of statistical significance used was  $p < 0.05$ . The skewness ratio (skewness value divided by the standard error) was applied to check for normality in the outcome instruments for each treatment group at all measurement points. Only the ISI and ESS instruments at baseline in the AA group showed a skewness ratio exceeding  $\pm 2$ , indicating that most measures did not deviate from normality. All analyses were performed with SPSS (version 21, IBM Corporation, Armonk, NY, USA).

# Results

## Patients' experience of auricular acupuncture during protracted withdrawal (Paper I)

The analysis resulted in seven categories of positive experiences and seven categories of negative experiences.

The positive experiences were: Relaxation and wellbeing, Peacefulness and harmony, New behaviours, Positive physical impact, Importance of context, Anxiety reduction and Reduced drug and alcohol consumption.

The negative experiences were: Nothing negative, Disturbing context, Short-term effect, Depending on someone else, Time-consuming, Physical distractions and Remaining cravings. The participants experienced a reduction in protracted withdrawal symptoms and improved subjective sleep quality. They also experienced a strong sensation of peacefulness, increased wellbeing, increased energy level, reduced physical discomfort, reduced irritability and fewer alcohol and drug cravings.

## Is Auricular Acupuncture as effective as Cognitive Behavioural Therapy for insomnia? (Paper II)

### Comparison between the CBT-i and the AA groups

The AA group was compared with the CBT-i group on the ISI, DBAS-16, ESS and HAD (A and B parts). The results were analysed to reveal changes over time from baseline to post-treatment and from baseline to the 6-month follow-up.

Significant between-group improvements occurred in favour of CBT-i in the primary outcome measure (ISI) at the post-treatment ( $p < 0.001$ ) and at the 6-month follow-up ( $p < 0.05$ ). In the DBAS-16, there was a significant change in favour of the CBT-i group at post-treatment ( $p < 0.01$ ); however, the result was not maintained at the 6-month follow-up. The between-group parameter estimates (PEs) after treatment and at the 6-month follow-up was 6.28 ( $p < 0.001$ ) and 2.95 ( $p < 0.05$ ) respectively for the ISI. For the DBAS-16, the between-group PEs were 1.51 ( $p < 0.01$ ) and 1.29 ( $p < 0.05$ ) after the treatment and at the 6-month follow-up respectively. For the HAD-D there were no

differences between the groups (both groups showed significant improvements). None of the groups showed changes in HAD-A or ESS. Comparisons between the groups are summarised in Figure 6.

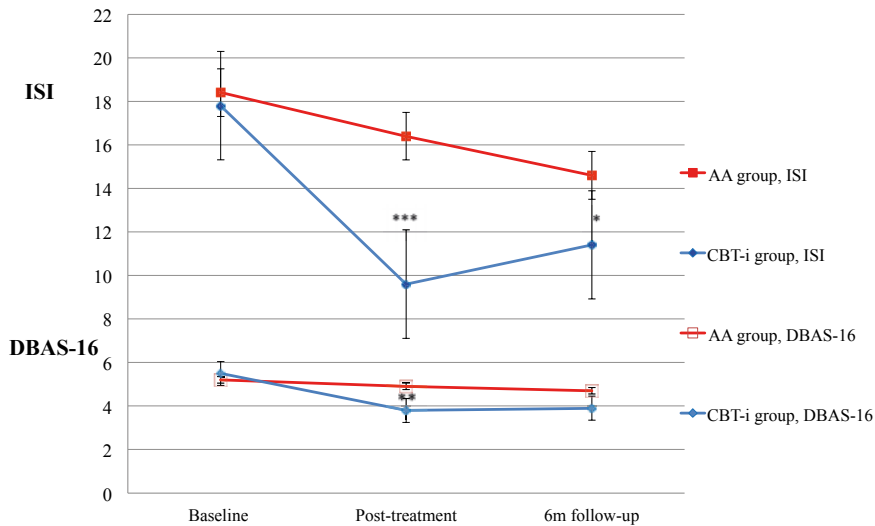


Figure 6: Changes in ISI and DBAS-16 scores between groups from baseline to post-treatment and from baseline to 6-month follow-up.

\* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\*  $p < 0.001$

ISI = Insomnia Severity Index, DBAS-16 = Dysfunctional Beliefs and Attitudes about Sleep scale.

## Within-group results

Within-group results are listed in Table 3.

### The AA-group

The ISI scores decreased at the post-treatment, PE -2.07 ( $p < 0.05$ ) and at the 6-month follow-up, PE -3.27 ( $p < 0.001$ ). Clinically significant post-treatment improvement as measured by the ISI showed zero cases of moderate improvement and two (8%) cases of marked improvement. At the 6-month follow-up there was one (5%) case with moderate improvement and three (14%) with marked improvement. HAD-D scores declined significantly from baseline to the 6-month follow-up, PE -0.70 ( $p < 0.05$ ). No significant changes were seen in DBAS-16, HAD-A or ESS.

### The CBT-i group

The ISI and DBAS-16 scores were found to decrease from baseline to post-treatment ( $p < 0.001$ ) and from baseline to the 6-month follow-up ( $p < 0.001$ ). The PE for the ISI was -8.16 ( $p < 0.001$ ) after treatment and -6.09 ( $p < 0.001$ )

at the 6-month follow-up. For the DBAS-16, the PE was -1.80 ( $p<0.001$ ) after treatment and -1.76 ( $p<0.001$ ) at the 6-month follow-up.

Clinically significant post-treatment improvements as measured by the ISI demonstrated that the CBT-i group had 3 (12%) cases with moderate improvement and 13 (52%) with marked improvement. At the 6-month follow-up, there were 2 (9%) cases with moderate improvement and 9 (39%) with marked improvement. There was also a significant decrease in HAD-D scores from baseline to the 6-month follow-up, PE -0.99 ( $p<0.05$ ). No improvements were seen in HAD-A or ESS.

Table 3.	Baseline		Post-treatment		6-month follow-up		Baseline versus post-treatment		Baseline versus 6-month follow-up	
	Estimate (SE)		Estimate (SE)		Estimate (SE)		Estimate (SE)		Estimate (SE)	
<b>ISI</b>										
AA	18.56 (0.70)		16.49 (0.94)		15.19 (0.94)		<b>-2.07 (0.78)*</b>		<b>-3.27 (0.84)**</b>	
CBT-i	17.75 (0.65)		9.6 (1.04)		11.66 (1.25)		<b>-8.16 (1.18)**</b>		<b>-6.09 (1.33)**</b>	
<b>DBAS-16</b>										
AA	5.20 (0.29)		4.83 (0.27)		4.70 (0.33)		-0.37 (0.29)		-0.50 (0.31)	
CBT-i	5.55 (0.25)		3.74 (0.34)		3.79 (0.44)		<b>-1.80 (0.34)**</b>		<b>-1.76 (0.39)**</b>	
<b>HAD-A</b>										
AA	5.58 (0.46)		4.69 (0.59)		5.22 (0.66)		-0.90 (0.46)		-0.36 (0.54)	
CBT-i	5.93 (0.58)		5.24 (0.55)		5.32 (0.58)		-0.68 (0.54)		-0.61 (0.56)	
<b>HAD-D</b>										
AA	5.33 (0.56)		4.94 (0.46)		4.63 (0.50)		-0.39 (0.40)		<b>-0.70 (0.37)*</b>	
CBT-i	5.78 (0.49)		5.29 (0.56)		4.78 (0.51)		-0.49 (0.63)		<b>-0.99 (0.49)*</b>	
<b>ESS</b>										
AA	4.56 (0.72)		3.75 (0.61)		4.44 (0.49)		-0.80 (0.54)		-0.12 (0.56)	
CBT-i	5.12 (0.67)		4.85 (0.72)		4.65 (0.68)		-0.28 (0.71)		0.48 (0.57)	

Table 3: Linear mixed models with within-group effects for AA and CBT-i.

Outcome variables are Insomnia Severity Index (ISI), Dysfunctional Beliefs and Attitudes about Sleep scale (DBAS-16), Hospital Anxiety and Depression scale (HAD-A, HAD-D) and Epworth sleepiness scale (ESS). \*p<0.05, \*\*p<0.001



## Auricular acupuncture versus cognitive behavioural therapy in the discontinuation of hypnotic drug usage and treatment effects on anxiety-, depression and insomnia symptoms (Paper III)

Results from the sleep diaries, which contained hypnotic drug consumption information, and the questionnaires, were analysed to examine treatment effects within and between the AA and CBT-i groups from treatment start to treatment stop.

### Hypnotic drugs

At baseline, the weekly hypnotic drug consumption was 6.9 tablets in the AA group and 5.9 in the CBT-i group. Because the participants were instructed to terminate their use of hypnotic drugs before treatment initiation there was a significant change in both groups between baseline and the start of treatment ( $p < 0.001$ ).

At the start of treatment 15 of 28 (54%) participants in the AA group and 18 of 29 (62%) in the CBT-i group had discontinued their hypnotic drug use. Both groups initiated their treatments taking only 1.8 tablets per week. Between the start of treatment and the end of treatment, there were small changes in hypnotic drug consumption: those in the AA group increased their consumption to 2.3 tablets a week and the participants in the CBT-i group decreased their consumption to 1.3 tablets per week. However, none of these changes were statistically significant, neither within nor between the two groups. Consequently, both groups managed to maintain hypnotic drug consumption below the inclusion criteria.

At the end of treatment, 17 of the 24 (71%) participants in the AA group and 21 of 24 (88%) participants in the CBT-i group discontinued their hypnotic drug consumption. 7 (29%) AA and 3 (13%) CBT-i participants continued their medication. These individuals, however, did reduce their hypnotic drug consumption to some extent though non-significantly: the AA participants reduced their consumption from a mean of 8.6 to 5.6 ( $z = 1.6$ ;  $p = 0.1$ ) tablets a week and the CBT-i participants from a mean of 5.6 to 4.2 ( $z = 0.5$ ;  $p = 0.6$ ) tablets a week.

### The questionnaires

The questionnaires were administered on two separate occasions, namely at the first and the last treatment sessions. The within group analysis showed that the CBT-i group improved in the ISI ( $p < 0.001$ ) and the AA group in the HAD-A ( $p < 0.05$ ) and HAD-D ( $p < 0.05$ ). Only the ISI showed a significant

interaction effect between groups ( $p < 0.001$ ). The results and effect sizes are summarised in Table 4.

Table 4.	Treatment start	Treatment stop	Within groups	Within groups	Between groups	Between groups
	Estimate (SE)	Estimate (SE)	Estimate (SE)	Cohen's <i>d</i>	Estimate (SE)	Cohen's <i>d</i>
<b>ISI</b>						
AA	17.0 (0.9)	15.7 (1.2)	1.3 (0.7)	0.39	<b>7.3 (1.4)**</b>	0.73
CBT-i	17.4 (0.9)	8.8 (1.4)	<b>8.6 (1.1)**</b>	1.40		
<b>HAD-A</b>						
AA	6.2 (0.7)	5.1 (0.7)	<b>1.1 (0.4)*</b>	0.44		
CBT-i	5.8 (0.7)	5.3 (0.7)	0.5 (0.5)	0.15	0.6 (0.7)	0.11
<b>HAD-D</b>						
AA	5.7 (0.6)	4.4 (0.6)	<b>1.3 (0.4)*</b>	0.58		
CBT-i	5.8 (0.6)	5.1 (0.6)	0.7 (0.6)	0.19	0.6 (0.8)	0.11

Table 4: Linear mixed models with within- and between-groups effects and effect sizes (Cohen's *d*) for auricular acupuncture (AA) and cognitive behavioural therapy for insomnia (CBT-i). The outcome variables, Insomnia Severity Index (ISI) and Hospital Anxiety Depression scale (HAD-A, HAD-D), are presented in Mean Estimates and Standard Error (SE). \*  $p < 0.05$  \*\*  $p < 0.001$

## The sleep diary

Measurements conducted during the first and the last week of treatment and effect sizes (Cohen's *d*) are given in Table 5.

The within-group results in the sleep diary indicate that the participants in the CBT-i group went to bed later ( $p < 0.001$ ) and fell asleep quicker ( $p < 0.05$ ) after the treatment than those in the AA group. Sleep efficiency ( $p < 0.001$ ) and their self-rated sleep quality ( $p < 0.05$ ) increased in the CBT-i group but not in the AA group. Both groups changed their time of waking up in the morning though in opposite directions: the CBT-i group rose earlier ( $p < 0.001$ ) and the AA group rose later ( $p < 0.05$ ). Time spent in bed decreased in the CBT-i group ( $p < 0.001$ ) and increased in the AA group ( $p < 0.05$ ). Concerning sleep offset and total sleep time, the groups did not differ significantly and no changes were observed. Because of missing data the number of night awakenings are not presented.

Table 5.

	Treatment start Estimate (SE)	Treatment end Estimate (SE)	Within groups Cohen's <i>d</i>	Between groups Cohen's <i>d</i>
<b>Bedtime</b> (hh:mm)				
AA	22:57 (9)	22:42 (9)	0.29	0.52
CBT-i	22:57 (7)	<b>23:27 (7)**</b>	0.90	
<b>Sleep onset latency</b> (hh:min)				
AA	01:05 (12)	01:15 (12)	0.12	0.46
CBT-i	01:10 (8)	<b>00:24 (7)**</b>	1.05	
<b>Sleep offset</b> (hh:mm)				
AA	06:13 (14)	06:21 (14)	0.16	0.13
CBT-i	06:50 (11)	06:17 (11)	0.10	
<b>Rising</b> (hh:mm)				
AA	07:16 (10)	<b>07:29 (10)*</b>	0.42	0.64
CBT-i	07:45 (10)	<b>07:05 (10)**</b>	0.83	

<b>Total sleep time</b> (number of hours)	AA	6.2 (0.3)	6.1 (0.3)	0.07	0.08
	CBT-i	5.5 (0.5)	5.5 (0.5)	0.12	
<b>Time in bed</b> (number of hours)	AA	8.3 (0.2)	<b>8.8 (0.2)*</b>	0.52	0.80
	CBT-i	8.7 (0.2)	<b>7.6 (0.2) **</b>	1.05	
<b>Sleep Efficiency (%)</b>	AA	74 (3)	73 (3)	0.13	0.56
	CBT-i	77 (2)	<b>89 (2)**</b>	1.08	
<b>Rated sleep quality (1-5)<sup>†</sup></b>	AA	2.9 (0.1)	2.8 (0.1)	0.20	0.55
	CBT-i	2.8 (0.2)	<b>3.4 (0.2)**</b>	0.90	

Table 5: Sleep diary variables: changes within AA- and CBT-i groups between the first and the last intervention week. Within- and between-group effect sizes (Cohen’s *d*) for both groups in sleep diary variables at treatment stop.

\* $p<0.05$ , \*\* $p<0.001$

<sup>†</sup> (1 = very bad, 5 = very good)

## Sleep patterns in a randomised controlled trial of auricular acupuncture and cognitive behavioural therapy for insomnia (Paper IV)

The actigraph results, presented in minutes and in percentages, as well as effect sizes (Cohen's *d*) and *p*-values, are listed in Table 6 and Table 7. The SF-12 results are shown in Table 8.

### Actigraph recording: within-groups results

Within-groups results are presented in Table 6. Significant interactions occurred within the groups. Compared with baseline, the participants in the CBT-i group went to bed 29.7 minutes (SE 7.2) later post-treatment ( $p<0.001$ ) and woke up and got up 43.3 minutes (SE 9.8) earlier than at baseline ( $p<0.001$ ). Furthermore they arose from bed 45.3 minutes (SE 10.0) earlier than at baseline ( $p<0.001$ ). The participants in the CBT-i group spent less time in bed (74.1 minutes, SE=18.9;  $p<0.001$ ) and increased their sleep efficiency by 4.6% (SE=1.4;  $p<0.01$ ). Sleep latency in the same group decreased by 16.4 minutes (SE 3.4) post-treatment ( $p<0.05$ ) and by 12.8 minutes (SE 4.0) at the 6-month follow-up ( $p<0.01$ ). There was also a significant decrease of the actual sleep time (38.7 minutes, SE=8.6;  $p<0.001$ ) and the actual wake time (29.9 minutes, SE=4.7;  $p<0.001$ ) after the treatment concluded.

The participants in the AA group woke up 24.1 minutes (SE 11.5) later ( $p<0.05$ ) and increased their time in bed with 17.2 minutes (SE 8.1) after the treatment ( $p<0.05$ ). They decreased their sleep latency by 7.2 minutes (SE 3.3) ( $p<0.05$ ) and increased their actual sleep time with 21.4 minutes (SE 7.0) post-treatment ( $p<0.01$ ).

Table 6. Within groups	Post-treatment vs Baseline Estimate (SE)	Cohen's <i>d</i>	6-mon follow-up vs Baseline Estimate (SE)	Cohen's <i>d</i>
<b>Bedtime (min)</b>				
AA	5.4 (11.1)	0.15	5.1 (12.5)	0.10
CBT-i	<b>29.7 (7.2)***</b>	1.21	18.0 (9.1)	0.50
<b>Fell asleep (min)</b>				
AA	-1.8 (11.0)	0.05	-1.1 (12.6)	0.02
CBT-i	14.0 (7.4)	0.55	5.4 (9.2)	0.15
<b>Woke up (min)</b>				
AA	<b>24.1 (11.5)*</b>	0.63	-6.5 (14.1)	0.12
CBT-i	<b>-43.3 (9.8)***</b>	1.43	-6.3 (11.9)	0.13
<b>Rising (min)</b>				
AA	21.8 (11.4)	0.57	-7.3 (13.9)	0.13
CBT-i	<b>-45.3 (10.0)***</b>	1.46	-6.8 (12.0)	0.14
<b>Time in bed (min)</b>				
AA	<b>17.2 (8.1)*</b>	0.64	-11.7 (10.3)	0.30
CBT-i	<b>-74.1 (18.9)***</b>	2.06	-23.6 (13.4)	0.44
<b>Sleep efficiency (%)</b>				
AA	1.5 (1.4)	0.33	1.9 (1.6)	0.30
CBT-i	<b>4.6 (1.4)**</b>	1.07	2.2 (1.6)	0.32
<b>Sleep latency (min)</b>				
AA	<b>-7.2 (3.3)*</b>	0.75	-5.6 (4.0)	0.36
CBT-i	<b>-16.4 (3.4)***</b>	1.58	<b>-12.8 (4.0)**</b>	0.79
<b>Actual sleep time (min)</b>				
AA	<b>21.4 (7.0)**</b>	0.93	1.0 (91)	0.03
CBT-i	<b>-38.7 (8.6)***</b>	1.37	-8.2 (11.4)	0.19
<b>Actual wake time (min)</b>				
AA	5.9 (5.8)	0.30	-4.8 (7.2)	0.17
CBT-i	<b>-29.9 (4.7)***</b>	1.94	-3.1 (6.0)	0.13

Table 6: Interactions and Cohen's delta (Cohen's *d*) within groups: the data from baseline to post-treatment and from baseline to the 6-month follow-up are presented as estimates and standard error (SE).

\*  $p < 0.05$ , \*\*  $p < 0.01$ , \*\*\*  $p < 0.001$



### Actigraph recording: between-groups results

Between-groups results are presented in Table 7. Significant interactions occurred between the AA and CBT-i groups from baseline to the post-treatment follow-up, but not between baseline and the 6-month follow-up. The groups differed in wake-up time, time of rising, time spent in bed, as well as their actual sleep time and actual wake time.

Compared with baseline measurements, the CBT-i group woke up and rose out of bed earlier, whereas the AA group woke up and rose out of bed later (66.6 minutes, SE=15.0;  $p<0.001$ ; 66.1 minutes, SE=15.1;  $p<0.001$ ) immediately post-treatment. Time spent in bed decreased in the CBT-i group and increased in the AA group (91.2 minutes, SE=13.6;  $p<0.001$ ). The CBT-i group decreased their actual sleep time and the actual wake time, whereas the AA group increased in these same parameters (60.2 minutes, SE=11.2;  $p<0.001$ ; 35.9 minutes, SE=7.4;  $p<0.001$ ).

Table 7. Between groups		Post treatment vs Baseline Estimate (SE)	Cohen's <i>d</i>	6-mon follow-up vs Baseline Estimate (SE)	Cohen's <i>d</i>
<b>Bedtime (min)</b>					
AA		-24.7 (13.1)	0.40	-12.9 (16.0)	0.14
CBT-i					
<b>Fell asleep (min)</b>					
AA		-16.3 (13.1)	0.26	-6.4 (16.1)	0.07
CBT-i					
<b>Woke up (min)</b>					
AA		<b>66.6 (15.0)***</b>	0.96	-0.8 (18.4)	0.01
CBT-i					
<b>Rising (min)</b>					
AA		<b>66.1 (15.1)***</b>	0.95	-1.4 (18.5)	0.01
CBT-i					
<b>Time in bed (min)</b>					
AA		<b>91.2 (13.6)***</b>	1.43	10.9 (17.0)	0.11
CBT-i					
<b>Sleep efficiency, (%)</b>					
AA		-3.1 (2.0)	0.35	-0.2 (2.2)	0.02
CBT-i					

<b>Sleep latency (min)</b>				
AA				
	9.2 (4.8)	0.46	7.1 (5.6)	0.22
CBT-i				
<b>Actual sleep time (min)</b>				
AA				
	<b>60.2 (11.2)***</b>	1.16	9.0 (14.5)	0.12
CBT-i				
<b>Actual wake time (min)</b>				
AA				
	<b>35.9 (7.4)***</b>	1.01	1.7 (9.4)	0.03
CBT-i				

Table 7: Interactions and Cohen’s delta (Cohen’s *d*) between the groups; between baseline to post-treatment and between baseline to 6-month follow-up, presented in estimates and standard error (SE). \*  $p \leq 0.05$ , \*\*  $p \leq 0.01$ , \*\*\*  $p \leq 0.001$

## SF-12

Measurements were made between and within the groups for the two dimensions of the SF-12 (MCS and PCS) at baseline, 1 week after the treatment ended and at the 6-month follow-up. No significant interactions between the groups were found.

Only the CBT-i group showed significant within-group changes, i.e. there were significant changes in both MCS and PCS at the post-treatment period compared with the baseline values (3.4, SE=1.7;  $p<0.05$ ; 3.3, SE=1.6;  $p<0.05$ ). For PCS, there was also a significant interaction at the 6-month follow-up compared with the baseline value (3.7, SE=1.8;  $p<0.05$ ). The within-groups results are shown in Table 8.

Table 8. Within groups	Baseline	Post-treatment	6-mon follow-up	Post-treatment vs Baseline	6-mon follow-up vs Baseline
	Estimate (SE)	Estimate (SE)	Estimate (SE)	Estimate (SE)	Estimate (SE)
<b>SF-12 MCS</b>					
AA	48.6 (49.3)	51.2 (49.4)	50.0 (49.6)	2.6 (1.4)	1.4 (1.8)
CBT-i	47.5 (49.6)	50.9 (49.1)	46.1 (49.3)	<b>3.4 (1.7)*</b>	-1.4 (2.3)
<b>SF-12 PCS</b>					
AA	48.3 (43.4)	48.5 (43.3)	48.2 (43.4)	0.2 (1.4)	-0.07 (1.5)
CBT-i	46.2 (43.4)	49.5 (43.5)	49.9 (43.0)	<b>3.3 (1.6)*</b>	<b>3.7 (1.8)*</b>

Table 8: Within-groups results for the Short Form 12 (SF-12) health status questionnaire, measuring the physical component summary (PCS) and the mental component summary (MCS) from baseline to post-treatment and from baseline to the 6-month follow-up. \* p<0.05

# Discussion

The aim of this thesis was twofold: to determine whether the results of Paper I were transferrable to a population with insomnia and to test the hypothesis that AA would be as effective as CBT-i in reducing insomnia symptoms. Thus, the RCT was conducted using both subjective and objective measurements in which the treatment outcomes were measured and compared over the shorter and longer term both within and between the groups.

## Main results

The main results in Paper I was that AA seemed to have a relaxing effect on the participants. More specifically, they experienced an increased sense of wellbeing and peacefulness as well as amelioration of their sleep difficulties. They did not experience any major negative effects of the AA treatment.

In Paper II, CBT-i proved to be a superior treatment compared to AA in decreasing insomnia symptoms and dysfunctional thoughts and beliefs about sleep in both the short- and long term. However, both the CBT-i and AA groups reduced their symptoms of depression at the 6-month follow-up.

The main results in Paper III were that the participants in both groups were equally successful in ending or at least maintaining a reduced intake of hypnotic drugs. The AA participants reduced their symptoms of anxiety and depression; the participants in the CBT-i group did not. The CBT-i group on the other hand reduced insomnia symptoms and improved their sleep diary parameters (e.g., total sleep time, time spent in bed and sleep onset latency), which was not the case for those in the AA group.

In Paper IV the actigraph recordings showed that the actual sleep time increased for the AA participants and decreased for the CBT-i participants after the treatment. The actigraph recordings at the 6-month follow-up revealed that the participants' sleep patterns had reverted to pre-treatment levels, however.

## Effects on insomnia symptoms

When comparing the two groups, CBT-i treatment reduced insomnia symptoms in the short- and long-term compared with AA treatment. The partici-

pants in the CBT-i group went from clinical to subclinical insomnia levels after treatment and maintained these levels 6 months later.

The sleep measurements of the ISI and the DBAS-16 were taken at the same time and in conjunction with the actigraph measurements. The objective actigraph recordings taken together with the subjective ISI and DBAS-16 measurements demonstrated that the CBT-i participants slept less but still benefitted from the treatment of their insomnia symptoms. Their reductions of both sleep latency and time awake, seem to have yielded a more recuperative sleep, a result supported by Kölling et al's. (2016) finding that rapid sleep onset was more strongly correlated with sleep efficiency than time spent in bed. [79].

The within-groups findings show that the AA participants reduced their insomnia symptoms, especially at the 6-month follow-up. These improvements however, were far too modest, with participants in the AA group remaining within the range for clinical insomnia (as measured by the ISI). As for changing dysfunctional thoughts and beliefs about sleep, the AA participants were not provided with any further coping strategy training programme for cognitive restructuring and, thus no improvements were seen. When it comes to objective measurements of AA, very few insomnia-related studies have objectively evaluated AA with actigraphy [31][49][80]. The increased actual sleep time for the AA participants is a new finding and thus an important contribution to the field.

The effectiveness of reducing insomnia symptoms as well as dysfunctional beliefs and thoughts about sleep with CBT-i is well documented [5][35][70][81][82]. Our results agree with those of previous studies. The reduction in severe symptoms of insomnia in combination with the sleep diary results and the reduction in dysfunctional beliefs and thoughts about sleep all indicate that the CBT-i manual has been carried out successfully. By performing the sleep restriction and learning how to change their behaviour and thoughts about sleep, the CBT-i participants successfully changed their sleep pattern and gained a more satisfying, yet initially shorter, sleep.

## Effects on related symptoms

Particularly noteworthy is that in this RCT the HAD scale was not used to diagnose anxiety or depression but merely to detect the occurrence of symptoms thereof. As a group, the participants were not diagnosed with anxiety or depression, but on an individual basis there was, to some extent, the occurrence of symptoms of anxiety or depression, or both. It is also important to keep in mind that the within-groups changes in the HAD scale were below the cut-off score for clinical symptoms of anxiety and depression. Nevertheless, there were trends towards symptom reduction. As reported in Paper III, the AA participants managed to reduce their anxiety and depressive symptoms during the treatment period; however, there were no significant im-

provements of insomnia symptoms in comparison with the CBT-i group. There were no reductions of anxiety- and depressive symptoms during the treatment period in the CBT-i group. They did, however, manage to reduce their depressive symptoms at the 6-month follow-up (as reported in Paper II).

The association between insomnia symptoms, anxiety and depression is well known [9][10][11]. Blom et al. (2015) found that treatment of insomnia could also reduce depressive symptoms for persons with both conditions [83]. The trend seen in depressive symptoms at the 6-month follow-up in the CBT-i group supports Blom's findings.

## Discontinuations of hypnotic drugs

When entering this study, the participants had persistent symptoms of insomnia despite treatment with hypnotic drugs. One of the inclusion criteria in the study was that the participants had to want to discontinue their use of insomnia drugs.

Based on the results of Study I, our hypothesis was that AA might provide some sort of support to the participants to discontinue psychoactive drug consumption by alleviating withdrawal symptoms and thereby be superior to CBT-i. The results in Paper III, however, showed that both groups were equally successful in ending their hypnotic drug consumption and thus the hypothesis was rejected.

Z-drugs are commonly used and have proven to be quite effective as a treatment option for insomnia [84]. Nevertheless, the risks must always be weighed against the benefits. Potential side effects (e.g., drowsiness or reduced alertness the day after intake, dizziness, headaches, risks of falls and tolerance issues, must be considered [85][86]. Because of the gaps in research in relation to the long-term effectiveness of z-drugs [33] further research is motivated.



# General discussion

## Clinical relevance

The clinical relevance of Paper II, III and IV is that the type of AA used in this study should not alone be recommended for insomnia symptoms. However AA proved to be as effective as CBT-i to reduce the use of hypnotic drugs.

The experience of insomnia symptoms is subjective and it is known that persons with insomnia tend to overestimate their sleep onset latency and underestimate their time spent in bed [28]. Short sleep duration may yield a satisfying sleep, and by cognitive reconstruction, CBT-i is highly effective in reducing symptoms of insomnia.

## Suggestions for future research

Stuyt et al. (2016) advocated that AA according to the NADA protocol should not be used as a stand-alone treatment, but as an adjunct treatment: “The NADA protocol is a very straightforward and low-cost tool that is not a stand-alone procedure, but aids in behavioural health treatment and recovery.” [87].

Previous research has shown that acupuncture and AA may reduce symptoms of anxiety [88][89][90] and depression [91]. Our results from Paper III (and to some extent those in Paper II) indicate that AA, according to the NADA protocol, seems to have an alleviating impact on symptoms of anxiety and/or depression, and thus further studies are prompted within fields in which these conditions occur.

Harvey and Tang (2003) called for further experimental investigations in conjunction with theory development to improve CBT-i [37]. Montserrat Sánchez-Ortuño and Edinger (2010) hypothesised that there are subgroups that may respond differently to manual-based CBT [38]. Hence, there is likely still considerable room for improvements of CBT-i as the first-line treatment of insomnia. One such improvement could be to test whether CBT-i would benefit with the addition of AA. Based on previous findings [54][92][93] as well as our results, AA seems to add a sense of relaxation and general wellbeing. Thus, one may speculate whether AA could be included as a potential add-on treatment to the CBT-i manual, making the combination potentially more successful therapy for insomnia.

## Limitations

The limitations for each paper are more thoroughly discussed within each article. When the RCT that were used in Papers II, III and IV was designed, the limitations of Paper I were discussed and taken into consideration. For instance, one limitation in Paper I was that the AA treatments were performed by the principal investigator alone (LB). To rectify these limitations in the RCT, one more acupuncturist was added. Nevertheless, LB was the head acupuncturist and met with the participants more times than the other acupuncturist, which may have affected the outcome.

Another limitation is that the CBT-i groups were not monitored, which means there is no way to know with certainty that all therapists conducted the therapy in the same way.

A further limitation concerns sample size. Small sample sizes can be problematic because they frequently violate normality and have limited statistical power. These limitations should be kept in mind when interpreting the current results. Furthermore, the results are limited to women in the age group represented in this study and hence we do not know whether the results could generalise to other age groups or to men. In addition, because of the low number of male participants, sex differences could not be determined. Further, no measurements of treatment preferences and expectations were performed. Such an analysis would have been of value in that there were participants in both groups who were dissatisfied with the group allocation, a situation that could have affected the credibility of the treatment results. Another limitation is that there was no wait-list or 'treatment-as-usual' control group in Papers II, III and IV and therefore it is uncertain whether the improvements in the AA group were caused by the treatment or by a placebo effect.

One of the strengths of this thesis is that a RCT with short- and long-term follow-ups was performed. A second strength was the use of subjective and objective measurements in the same study. The immediate treatment effects of the AA therapy according to the NADA protocol for insomnia disorder, which has not been evaluated before, have been explored, making this thesis a contribution to the field of AA treatment for insomnia.

# Conclusions

## Paper I

The treatment used in Paper I was found to appreciably help the participants tolerate protracted withdrawal from drugs. This study supports performing further research on AA per the NADA protocol in addiction treatment to reduce suffering during lengthy withdrawal periods and in other contexts (e.g., for insomnia symptoms as well as depressive and anxiety disorders).

## Paper II

CBT-i was superior to AA in reducing insomnia symptoms in both the short and long run. Both groups experienced significant long-term reduction of depressive symptoms. Compared to CBT-i, however, AA, as offered in this study, cannot be considered an effective stand-alone treatment for persons with insomnia disorder.

## Paper III

Both groups managed to maintain a decreased intake of hypnotic drugs at the end of the treatment when compared to baseline measurement. Symptoms of anxiety and depression improved only in the AA group. Immediate treatment effects show that the insomnia symptoms improved for the CBT-i group but not for the AA group. Further studies investigating AA for anxiety and depression are motivated.

## Paper IV

The results from the objective actigraph recordings showed that the AA group slept more and the CBT-i group less after the treatment and that sleep patterns in both groups reverted to pre-treatment levels after 6 months.

The comprehensive conclusion from the RCT is that AA, as administered in this study, was not as good as CBT-i in treating insomnia. Accordingly it

should not be used or recommended as a stand-alone treatment for insomnia. Taken together, the results of Papers II and IV demonstrate that prolonged sleep time does not necessarily yield better sleep, and that the perception of insomnia symptoms is not inevitably affected by sleep duration. As for ending the use of hypnotic drugs however, AA was as effective as CBT-i. Moreover, AA was more successful than CBT-i in reducing symptoms of anxiety and depression in the short run.

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